



Zimmer, Inc.
Nicole Meredith
Regulatory Affairs Project Manager
P.O. Box 708
Warsaw, Indiana 46581-0708

January 30, 2018

Re: K173417

Trade/Device Name: Zimmer® Persona® Personalized Knee System
Regulation Number: 21 CFR 888.3565
Regulation Name: Knee Joint Patellofemorotibial Metal/Polymer Porous-Coated Uncemented
Prosthesis
Regulatory Class: Class II
Product Code: MBH, JWH
Dated: October 30, 2017
Received: November 1, 2017

Dear Nicole Meredith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Katherine D. Kavlock -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

Indications for Use

510(k) Number (if known)
K173417

Device Name
Zimmer® Persona® Personalized Knee System

Indications for Use (Describe)

This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
- Moderate valgus, varus, or flexion deformities.
- The salvage of previously failed surgical attempts or for a knee in which satisfactory stability in flexion cannot be obtained at the time of surgery.

Porous coated components may be used cemented or uncemented (biological fixation). All other femoral, tibial baseplate, and all-polyethylene (UHMWPE and VEXLPE) patella components are indicated for cemented use only.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

In accordance with 21 CFR §807.92 and the Safe Medical Devices Act of 1990, the following information is provided for the Zimmer® Persona® The Personalized Knee System 510(k) premarket notification. The submission was prepared in accordance with the FDA guidance document, 'Format for Traditional and Abbreviated 510(k)s', issued on August 12, 2005.

Sponsor: Zimmer, Inc.
P.O. Box 708
Warsaw, IN 46581-0708
Establishment Registration Number: 1822565

Contact Person: Nicole J. Meredith
Regulatory Project Manager
Telephone: (574) 377-3718
Fax: (574) 372-4710

Date: October 30, 2017

Subject Device: **Trade Name:** Zimmer® Persona® The Personalized Knee System

Common Name: Knee Prostheses

Classification Name:

- MBH – Prosthesis, Knee, Patello/Femorotibial, Semi-Constrained, Uncemented, Porous, Coated, Polymer/Metal/Polymer (21 CFR 888.3565)
- JWH – Prosthesis, Knee, Patellofemorotibial, Semi-Constrained, Cemented, Polymer/Metal/Polymer (21 CFR 888.3560)

Predicate Device(s): K121771, Zimmer Persona The Personalized Knee System, cleared November 7, 2012

K072160, NexGen® Trabecular Metal® Tibial Tray, cleared September 5, 2007

Purpose and Device Description: The purpose of this submission is for a specification update to the Persona Trabecular Metal tibial component, as well as to introduce new tibial instrumentation unique to the device. These modifications do not change the intended use or fundamental scientific technology of the device.

**Intended Use and
Indications for Use:**

This device is indicated for patients with severe knee pain and disability due to:

- Rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Collagen disorders, and/or avascular necrosis of the femoral condyle.
- Post-traumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy.
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**Summary of Technological
Characteristics:**

The rationale for substantial equivalence is based on consideration of the following characteristics:

- **Intended Use:** Identical
- **Indications for Use:** Identical
- **Materials:** Identical
- **Design Features:** Same implant design features with updated print specification and new implant-specific instrumentation
- **Sterilization:** Identical

**Summary of Performance Data
(Nonclinical and/or Clinical)**

- **Non-Clinical Tests:**
 - Micromotion analysis
 - Implant-to-bone interface analysis
 - Tibial perforation analysis
 - Testing to establish product non-pyrogenicity
- **Clinical Tests:**
 - Clinical data was not deemed necessary for the subject device.

**Substantial Equivalence
Conclusion**

The subject device has the same intended use and indications for use as the predicate devices. The subject device has similar technological characteristics to the predicates, and the performance data and analyses demonstrate that:

- any differences do not raise new questions of safety and effectiveness; and
- the proposed device is at least as safe and effective as the legally marketed predicate devices.